

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
*(Not for submission under 37 CFR 1.99)*

Application Number	10719553
Filing Date	2003-11-20
First Named Inventor	Ispen et al.
Art Unit	1644
Examiner Name	N. M. Rooney
Attorney Docket Number	27554-0009002

U.S. PATENTS							<a href="#">Remove</a>
Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	
	1						

If you wish to add additional U.S. Patent citation information please click the Add button. [Add](#)

U.S. PATENT APPLICATION PUBLICATIONS							<a href="#">Remove</a>
Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	
	1						

FOREIGN PATENT DOCUMENTS							<a href="#">Remove</a>	
Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	Ts
	1	WO 92/10775	DK		1992-06-25	NOVO NORDISK A/S		<input type="checkbox"/>
	2	WO 99/47680	DK		1999-09-23	ALK-ABELLO A/S		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button [Add](#)

NON-PATENT LITERATURE DOCUMENTS		<a href="#">Remove</a>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10719553	
Filing Date	2003-11-20	
First Named Inventor	Ispen et al.	
Art Unit	1644	
Examiner Name	N. M. Rooney	
Attorney Docket Number	27554-0009002	

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	Ts
	1	FERRERIA, F. et al., Modulation of IgE reactivity of allergens by site-directed mutagenesis: potential use of hypoallergenic variants for immunotherapy; <i>Faseb J.</i> , Vol. 12, pp. 231-242, (1998)	<input type="checkbox"/>
	2	WIEDEMANN, P. et al., Molecular and Structural Analysis of a Continuous Birch Profilin Epitope Defined by a Monoclonal Antibody; <i>The Journal of Biological Chemistry</i> , Vol. 271, No. 47, pp. 29915-29921, (1996)	<input type="checkbox"/>
	3	SMITH, A. M. et al., Localization of antigenic sites on Der p 2 using oligonucleotide-directed mutagenesis targeted to predicted surface residues; <i>Clinical and Experimental Allergy</i> , Vol. 27, pp. 583-599, (1997)	<input type="checkbox"/>
	4	SPANGFORT, M. D. et al., Three-Dimensional Structure and Epitopes of Bet v 1; <i>International Archive of Allergy and Immunology</i> , Vol. 119, pp. 243-245, (1997)	<input type="checkbox"/>
	5	HOFFMAN, D. R. , Allergens in Hymenoptera venom XXV: The amino acid sequences of antigen 5 molecules and the structural basis of antigenic cross-reactivity; <i>The Journal of Allergy and Clinical Immunology</i> , Vol. 82, No. 5, pp. 708-716, (1993)	<input type="checkbox"/>
	6	BEEZHOLD, D. H. et al., IgE epitope analysis of the hevein preprotein; a major latex allergen; <i>Clinical and Experimental Immunology</i> , Vol. 108, pp. 114-121, (1997)	<input type="checkbox"/>
	7	TAKAI, T. et al., Engineering of the major house dust mite allergen Der f2 for allergen-specific immunotherapy; <i>Nature Biotechnology</i> , Vol. 15, pp. 754-758, (1997)	<input type="checkbox"/>
	8	FIEBIG, H. , Immunologische Aspekte der spezifischen Immuntherapie (Hyposensibilisierung) Teil I: Die Steuerung der IgE-Synthese; <i>Interdisciplinary Journal of Allergy and Environmental Medicine</i> , pp. 3-12, (1995)	<input type="checkbox"/>
	9	BLASER, K. , Immunologische Grundlagen der allergenspezifischen Immuntherapie, <i>Zentrum Fur Rhinologie und Allergologie</i> , Vol. 35, No. 5, pp. 217-222, (2009)	<input type="checkbox"/>
	10	KAHLERT, H. et al. , Characterization of Hypoallergenic Recombinant Bet v 1 Variant as a Candidate for Allergen-Specific Immunotherapy; <i>International Archives of Allergy and Immunology</i> , Vol. 145, pp. 193-206, (2008)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10719553
Filing Date	2003-11-20
First Named Inventor	Ispen et al.
Art Unit	1644
Examiner Name	N. M. Rooney
Attorney Docket Number	27554-0009002

11	STANLEY, J. S. et al., Identification and Mutational Analysis of the Immunodominant IgE Binding Epitopes of the Major Peanut Allergen Ara h 2; Archives of Biochemistry and Biophysics, Vol. 342, No. 2, pp. 244-253, (1997)	<input type="checkbox"/>
12	SCHRAMM, et al., Sequenzspezifische Mutagenese des Graspollenallergens rPhl p 5b: Allergenvarianten mit reduzierter IgE-Reaktivität, aber konservierter T-Zell-Reaktivität, Mainzer Allergie-Workshop, Interdisciplinary Journal of Allergy and Environmental Medicine, Vol. 7, pp. 24, (1996)	<input type="checkbox"/>
13	COLOMBO, P. et al., Identification of an Immunodominant IgE Epitope of the <i>Parietaria judaica</i> major Allergen; The Journal of Immunology, Vol. 160, pp. 2780-2785, (1998)	<input type="checkbox"/>
14	YUSUKE, ABE et al., Epitope Analysis of Birch Pollen Allergen in Japanese Subjects; Journal of Clinical Immunology, Vol. 17, No. 6, pp. 485-493, (1997)	<input type="checkbox"/>
15	SPARHOLT, S. H. et al., Crossreactivity and T-cell epitope specificity of Bet v 1-specific T cells suggest the involvement of multiple isoallergens in sensitization to birch pollen; Clinical and Experimental Allergy, Vol. 27, pp. 932-941, (1997)	<input type="checkbox"/>
16	LUZZAGO, A. et al., Mimicking of discontinuous epitopes by phage-displayed Peptides, I. Epitope mapping of human H ferritin using a phage library of constrained Peptides; Gene, Vol. 128, pp. 51-57, (1993)	<input type="checkbox"/>
17	AKI, T. et al., Structure of IgE Epitopes on a New 39-kD Allergen Molecule from the House Dust Mite, <i>Dermatophagoides farinae</i> ; International Archives of Allergy Immunology, Vol. 103, pp. 357-364, (1994)	<input type="checkbox"/>
18	WESLEY BURKS, A. et al., Mapping and mutational analysis of the IgE-binding epitopes on Ara h 1, a legume cinnolin protein and a major allergen in peanut hypersensitivity; Eur. J. Biochem., Vol. 245, pp. 334-339, (1997)	<input type="checkbox"/>
19	GAJHEDE, M. et al., X-ray and NMR structure of Bet v 1, the origin of birch pollen allergy, Nature Structural Biology, Vol. 3, No. 12, pp. 1040-1045, (1996)	<input type="checkbox"/>
20	SPANGFORT, M. D. et al., Crystallization and Preliminary X-Ray Investigation at 2.0 Å Resolution of Bet v 1, a Birch Pollen Protein Causing IgE-Mediated Allergy; Proteins: Structure, Function and Genetics, Vol. 26, pp. 358-360, (1996)	<input type="checkbox"/>
21	LU, G. et al., Sequence Analysis and Antigenic Cross-reactivity of a Venom Allergen, Antigen 5, from Hornets, Wasps, and Yellow Jackets; The Journal of Immunology, Vol. 150, No. 7, pp. 2823-2830, (1993)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10719553
Filing Date	2003-11-20
First Named Inventor	Ispen et al.
Art Unit	1644
Examiner Name	N. M. Rooney
Attorney Docket Number	27554-0009002

22	IPSEN, H. et al., Specificity mapping of patients IgE response towards the tree pollen major allergens Aln g 1, Bet v 1 and Cor a 1; Clinical and Experimental Allergy, Vol. 22, pp. 391-399, (1992)	<input type="checkbox"/>
23	FERREIRA, F. et al., Modulation of IgE-Binding Properties of Tree Pollen Allergens by Site-Directed Mutagenesis; Advances in Experimental Medicine and Biology, Vol. 409, pp 127-135, (1996)	<input type="checkbox"/>
24	SMITH, A. M. et al., Recombinant allergens for immunotherapy: A Der p 2 variant with reduced IgE reactivity retains T-cell epitopes; J. Allergy Clin. Immunol., Vol. 101, No. 3, pp. 423-425, (1998)	<input type="checkbox"/>
25	FABER, C. et al., Secondary Structure and Tertiary Fold of the Birch Pollen Allergen Bet v 1 in Solution; The Journal of Biological Chemistry, Vol. 271, No. 32, pp. 19243-19250, (1996)	<input type="checkbox"/>
26	DALUM, I. et al., Induction of Cross-Reactive Antibodies Against A Self Protein By Immunization With a Modified Self Protein Containing a Foreign T Helper Epitope; Molecular Immunology, Vol. 34, No. 16-17, pp. 1113-1120, (1997)	<input type="checkbox"/>
27	SKOLNICK, J. et al., From genes to protein structure and function: novel applications of computational approaches in the genomic era; Tibtech, Vol. 18, pp. 34-39, (2000)	<input type="checkbox"/>
28	BLUMENTHAL, M. et al., Definition of an Allergen (Immunobiology); Allergens and Allergen Immunotherapy, pp. 37-50, (2004)	<input type="checkbox"/>
29	RAO, S., PV. et al., B- and T-cell epitopes of tropomyosin, the major shrimp allergen; Allergy, Vol. 53 (Suppl 46), pp. 44-47, (1998)	<input type="checkbox"/>
30	AALBERSE, R. C., Ph.D., Molecular mechanisms in allergy and clinical immunology; J. Allergy Clin. Immunol., Vol. 106, No. 2, pp. 228-238, (2000)	<input type="checkbox"/>
31	KING, T. P., et al., Structure and Biology of Stinging Insect Venom Allergens; International Archives of Allergy and Immunology, Vol. 123, pp. 99-106, (2000)	<input type="checkbox"/>
32	MULLER, W. D., et al., Mapping of T-cell epitopes of Phi1 p 5: evidence for crossreacting and non-crossreacting T-cell epitopes within Phi1 p 5 isoallergens; Clinical and Experimental Allergy, Vol. 28, pp. 1538-1548, (1998)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10719553
Filing Date	2003-11-20
First Named Inventor	Ispen et al.
Art Unit	1644
Examiner Name	N. M. Rooney
Attorney Docket Number	27554-0009002

33	SCHRAMM, G. et al., "Allergen engineering": variants of the grass pollen allergen rPhl p 5b for efficient and safer allergen-specific immunotherapy; Oral Communication - Allergens, FC020, pp. 54-55, (1998)	<input type="checkbox"/>
34	SUPHIOGLU, C. et al., Molecular basis of IgE-recognition of Lol p 5, a major allergen of rye-grass pollen; Molecular Immunology, Vol. 35, pp. 293-305, (1998)	<input type="checkbox"/>
35	VALENTA, R., Genetically Engineered and Synthetic Allergen Derivatives: Candidates for Vaccination against Type 1 Allergy; Biol. Chem., Vol. 380, pp. 815-824, (1999)	<input type="checkbox"/>
36	MIRZA, O. et al., Dominant Epitopes and Allergic Cross-Reactivity: Complex Formation Between a Fab Fragment of a Monoclonal Murine IgG Antibody and the Major Allergen from Birch Pollen Bet v 1; Journal of Immunology, Vol. 165, No. 1, pp. 331-338	<input type="checkbox"/>
37	PUNNONEN, J., Molecular Breeding of Allergy Vaccines and Antiallergic Cytokines; International Archive of Allergy and Immunology, Vol. 121, pp. 173-182, (2000)	<input type="checkbox"/>
38	SPANGFORT, M. D., The Potential Use of Recombinant Allergens for Immunotherapy; J. Allergy Clin. Immunol., Vol. 105, No. 1, Part 2, pp. S169	<input type="checkbox"/>
39	LARSEN JORGEN NEDERGAARD et al., Toward a Unifying Theory for the Mechanism of Specific Allergy Vaccination; J. Allergy Clin. Immunol., Vol. 105, No. 1, Part 2, S311	<input type="checkbox"/>
40	SINGH, M. B. et al., Genetically Engineered Plant Allergens with Reduced Anaphylactic Activity; International Archives of Allergy and Immunology, Vol. 119, pp. 75-85, (1999)	<input type="checkbox"/>
41	Notice of Opposition filed by Merck Patent GmbH in counterpart application EP99907345.5 (EP 1 062 341 B1) on September 17, 2008	<input type="checkbox"/>
42	Observations on the opposition against EP 1 062 341 B1 by Merck Patent GmbH filed on February 2, 2010 on behalf of patentee Alk-Abello A/S	<input type="checkbox"/>
43	Notice of Opposition filed by Merck Patent GmbH for EP01996610.0 (EP 1 373 510 B1) on November 19, 2008	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10719553
Filing Date	2003-11-20
First Named Inventor	Ispen et al.
Art Unit	1644
Examiner Name	N. M. Rooney
Attorney Docket Number	27554-0009002

44

Observations on the opposition against EP 1 373 510 B1 by Merck Patent GmbH filed on March 31, 2010 on behalf of patentee Alk-Abello A/S



If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.